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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,650	02/19/2004	Robert Bargatze	MONT-038/03	2153

58249 7590 08/09/2007  
COOLEY GODWARD KRONISH LLP  
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WASHINGTON, DC 20036-2402

EXAMINER
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HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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08/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/780,650

Applicant(s)

BARGATZE ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on November 6, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 55-80 is/are pending in the application.
- 4a) Of the above claim(s) 77-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 55-80 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/1/05 & 6/17/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I in the reply filed on November 6, 2006 is acknowledged. Claims 76-80 have been withdrawn. Claims 55-76 are under consideration in this office action.

***Priority***

2. If applicant desires benefit of a previously filed application under 35 U.S.C. 119, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

**Specification**

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 55-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutler et al. (US Patent 5,578,309) in view of Jutila et al., (1997. J. Exp. Med. Vol. 186(10):1701-1711.

The claims are drawn to a method for identifying pathogen-ligand adhesive interactions under shear flow conditions wherein the ligand is immobilized on a substrate. The dependant claims are drawn to specific ligands, flow conditions, and substrate types.

Cutler et al., teach studies on adherence properties of *C. albicans* are important in gaining an understanding of *C. albicans* interactions with its host (col. 3, lines 66-68). The ability to bind to mucus and epithelial surfaces likely plays a critical role in maintaining *C. albicans* at these locations (col. 4, lines 1-3). The fungus also shows

Art Unit: 1645

adherence specificities for selected populations of splenic and lymph node macrophages Evidence that *C. albicans* binds via a unique adhesion system on phagocytic cells in the marginal zone of the mouse spleen (col. 3, lines 3-10).

Some adhesins have integrin-like activity in that they act as receptors for mammalian proteins such as iC3b, fibronectin, laminin and fibrinogen; one adhesin has lectin-like activity (col. 3, lines 33-40). Cutler et al., disclose the identification of the participating ligands and development of inhibitory peptides (col. 3, lines 38-40). Pathogens are the surface of hydrophilic yeast cells of *C. albicans* and have a fibrillar appearance both in vitro and in vivo (col. 3, lines 52-55). Cutler et al., teach the function of moieties on the fungal cell surface and adherence properties, including candidal-host interactions (col. 9, lines 18-24). Example 1 teach a microsphere assay which detects surface hydrophobic interactions within *C. albicans* populations. The cells are immobilized on the polystyrene microspheres suspended in buffer and subjected to shear flow conditions (col. 10, lines 5-16). Yeast cells are analyzed to determine whether there is attachment (col. 10, lines 16-19). Example 2 teaches tissue adherence characteristics of *C. albicans* and adhesin isolation. By use of an ex vivo adherence assay, the adherence characteristics of hydrophilic and hydrophobic yeast cells to mouse splenic and lymph node tissue was examined; binding of *C. albicans* yeast cells to mouse popliteal lymph node tissue is mediated by macrophages (col. 10, lines 30-45). However Cutler et al., does not specifically recite the specific techniques of the microsphere or adherence assays using shear flow conditions.

Jutila et al., teach characterization of an adhesion molecule that mediates rolling on cytokine and lipopolysaccharide-stimulated endothelial cells under flow conditions. The authors teach a capillary tube shear dependant rolling assay wherein the measurement of the interaction of the leukocytes with cells expression adhesion molecules under controlled shear forces is disclosed (page 1702, col.2). Endothelial cells were seeded into the tubes; tubing was attached to each end of the capillary tube to form a closed system in which fluid and cells could be recirculated using a variable peristaltic pump (page 1702, col.2). Purified  $\gamma/\delta$  T cells or neutrophils were injected into the system (page 1702, col.2). The authors used cytokine-stimulated endothelial cells, in the assays also (page 1702, col. 2). Data was recorded in the field of view versus time (page 1702, col. 2).

Therefore it would have been prima facie obvious at the time of applicants invention to modify the method of Cutler et al., to include the specific steps as taught by Jutila et al., The art teaches the identification and characterization of pathogen-ligand adhesive interactions, along with a variety of adhesion identification methods including the microsphere, capillary tube and other adherence assays therefore no more than routine skill would have been required to use shear flow conditions when the art teaches that shear flow determines the interaction. Furthermore, one of ordinary skill in the art would have had a reasonable expectation of success in modifying the method of identification to include shear flow condition using an immobilized ligand when only routine skill is required to exchange and/or use an alternative ligands and substrates in conjunction with adherence determination.

Art Unit: 1645

***Prior Art***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Beachy teach bacterial adherence: adhesion-receptor interactions. Burgess et al., teach analysis of adhesion to mammalian cells using monoclonal antibodies. Rozdzinski et al., (J. Clin. Invest. 1995. Vol. 95:1078-85) teach similar methods.

***Conclusion***

6. No claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines  
January 17, 2007

### ***Conclusion***

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1645

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Ja-Na Hines   
January 17, 2007